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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,931	08/02/2001	Debra L. Shade	1812 US	8818

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ALCON RESEARCH, LTD.
R&D COUNSEL, Q-148
6201 SOUTH FREEWAY
FORT WORTH, TX 76134-2099

EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,931	SHADE ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *18 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. New claims 1, 4-7, 8, 11 & 12-14 use improper Markush language. Elements within a Markush group are required to possess some structural similarity (e.g., be classified within the same class). See M.P.E.P. 2173.05(h). For example, the originally elected/presented invention was classified in Class/subclass 514/12, as it related to using the ADNF polypeptide. In contrast, peptido-mimetics are from Class/subclass 530/323, while small molecule analogues' or upregulating agents' class/ subclass "vary" depending on the chemical composition of such, while expression vectors are classified in 514/44, and while encapsulated secreting cells are classified in 424/93.1.

2. Newly submitted claims 1-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Originally presented/elected invention was using ADNF, which is now cancelled. However, because ADNF-9 and ADNF-14 appear to be fragments of ADNF, these fragments of ADNF are interpreted as being part of the originally elected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim directed toward "peptidomimetics, small molecule analogues, agents that upregulate endogenous ADNF, expression vectors that induce ADNF expression" in base claims 1 & 8, as well as "encapsulated cells which secrete the compound" in base claims 4 & 11 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. In other words, failure to separate nonelected inventions from the elected invention will be held as nonresponsive, and may result in ABANDONMENT of this application.

3. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for decreasing retinal ganglion cell death comprising administering an effective amount of an ADNF molecule that is structurally and functionally defined, does not reasonably provide enablement for treating unknown "damage"/ cells/ neurons with structurally and functionally uncharacterized proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper No: 20031112, and as follows.

Applicants argue on page 4 of the response that the amended claims address the enablement issues raised in the previous Office. In contrast to Applicants' assertions, claim 1 still recites "treating retinal and/or optic nerve head damage..." with structurally and functionally uncharacterized compounds, such as ADNF-9 or ADNF-14, which therefore, remains not enabled for the reasons extensively made of record in the previous Office action; consistent the teachings of Jackowski, Rapp and Rudinger previously made of record. Second, although a distinguishable and enabled assay is recited in new claims 8-14, these claims also fail to recite any structurally and functionally characterized compounds that are required for use in these methods; thereby, also being not enabled for

the reasons previously made of record, which are consistent with the teachings of Rudinger previously made of record.

Accordingly, as it relates to the compounds required to practice the currently claimed methods, it was held in *Ex parte Maizel* (27 USPQ2d 1662 at 1665) that:

> Appellants have not chosen to claim the DNA [product] by what it is but, rather, by what it does, i.e., encoding either a protein exhibiting certain characteristics, *or* a biologically functional equivalent thereof. Appellants' claims might be analogized to a single means claim of the type disparaged by the Court of Customs and Patent Appeals in *In re Hyatt,* 708F.2d 712, 218 USPQ 195 (Fed. Cir. 1983). The problem with the phrase "biologically functional equivalent thereof" is that it covers any conceivable means, i.e., cell or DNA, which achieves the stated biological result while the specification discloses, at most, only a specific DNA [product] segment known to the inventor. Clearly the disclosure is *not commensurate in scope with the claim*s [emphasis added].

Thus, in that no structure and little functional language (i.e., ADNF-9, ADNF-14) are recited in the claims, the claims encompass using any "biologically functional equivalent" product, which the court held as not enabled.

4. Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gozes et al (WO 98/35042; IDS Ref # AN) for the reasons made of record in Paper No: 20031112, and as follows.

Applicants argue on pages 4-5 of the response that "Gozes discusses the use of ADNF-III, also *known as ADNF* [emphasis added]", that "Gozes further describes the *discovery of ADNF* (also known as ADNF-I) [emphasis added]", and cite *Verdegaal Bros., Inc., Minnesota Mining & Mfg.*, and *Atlas Powder Co.* However, in contrast to Applicants' assertions, nowhere in the specification does it state that "ADNF III and ADNF are not the same protein". In contrast, page 1 (lines 7-9) merely states that "[t]he

present invention is directed to the use of Activity Dependent Neurotrophic Factor (ADNF)". Moreover, the specification and Applicants admit in their response that Gomez's protein is also referred to "as ADNF"; thereby, constituting admitted prior art. Thus, Applicants' arguments are moot, because the claims fail to recite any distinguishable structural claim limitations that do not encompass Gozes' invention.

In summary, Gozes et al teach treatment of "retinal neuronal degeneration" with pharmaceutically effective amounts of ADNF polypeptides, and fragments thereof (pgs. 60, line 12; pgs. 61-63), which include ADNF-9 & ADNF-14 when, for example, x is 0 and y is one, and when x & y are both three, respectively, in the generic amino acid sequence disclosed (pg. 61, line 8), and in which "retinal neuronal degeneration" is a "retinal and/or optic nerve head damage" (as also acknowledged on page 3 of the instant specification). In that the only reasonable way of treating "retinal neuronal degeneration" is by "decreasing retinal ganglion cell death", the limitations of new claims 1-3 & 8-10 are anticipated. In that Gozes et al teach on page 61 "a variety of drug delivery systems" (i.e., including "topical administration, ocular injection, implantation of a slow release device, bolus"), as well as "topical... or local administration" and administration parenterally (e.g., pg. 62, lines 3-19), in which "topical", local and administration parenterally to the eye can only be reasonably accomplished through either "bolus", "ocular injection", "intraocular injection" and/or "periocular injection", claims 4-7 & 12-14 are anticipated.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Robert C. Hayes, Ph.D.
May 27, 2004

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600